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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/397,967	09/17/1999	JAMES IHLE	0656.0370004	9463

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	**PAPER NUMBER**
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/397,967	Applicant(s) IHLE ET AL.	
	Examiner Quang Nguyen, Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35,36,42 and 45-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35,36,42 and 45-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

The request filed on February 07, 2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/397967 is acceptable and a CPA has been established. An action on the CPA follows.

Applicants' amendment filed on December 09, 2002 in Paper No. 17 has been entered.

Amended claims 35-36, 42 and 45-47 are pending in the present application, and they are examined on the merits herein.

Priority

Examiner notes that the paragraph on cross-reference to related applications on page 1 does not follow the title of the invention or appear as the first paragraph of the specification. Additionally, please update the paragraph with related applications appearing in the Declaration (e.g., 08/282,012; 08/118,968 as well as 08/665,574).

The instant claims are given the priority date of 7/29/1994. This is because the initial disclosure of SEQ ID NO:16 only appears in the application with the Serial No. 08/282,012 with a filing date of 7/29/1994, which is a CIP of the application with the Serial No. 08/097,997, now U.S. Patent No. 5,728,536, and a CIP of the application with the Serial No. 08/118,968, now abandoned.

Claim Rej ctions - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35,36, 42, 45-46 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 35 and its dependent claims, it is unclear what is encompassed by the phrase "encoding 400 contiguous amino acids or less of a Jak 3 peptide of SEQ ID NO:16, wherein said peptide contains the sequence of SEQ ID NO:15 which includes the Jak3 autophosphorylation site". This is because SEQ ID NO:16 does not contain the sequence of SEQ ID NO:15 (AKLLPL**D**KDYYVVREPG), and instead it contains the sequence of AKLLPL**G**KDYYVVREPG (see SEQ ID NO:16 and Fig. 6). The metes and bounds of the claims are not clearly determined.

Similarly, it is unclear what is encompassed by the phrase "a DNA sequence encoding amino acids of a Jak3 peptide of SEQ ID NO:16, wherein said peptide contains the sequence of SEQ ID NO:15, which includes the Jak3 autophosphorylation site" for the same reason set forth immediately above.

In claim 47, it is unclear what is encompassed by the phrase "wherein said molecule encodes a Jak3 polypeptide that is at least 80-99% homologous to the amino acid sequence of SEQ ID NO:16". How can a nucleic acid comprising a sequence encoding at most 400 tontiguous amino acid residues of SEQ ID NO:16, also encode a

polypeptide that is 80%-99% homologous to SEQ ID NO:16, which is 1,099 amino acid residues in length? The metes and bounds of the claim are not clearly determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 35 is rejected under 35 U.S.C. 102(a) as being anticipated by Fuortes (Accession U08340, April 21, 1994).

The claim is drawn to an isolated DNA molecule comprising a DNA sequence encoding 400 contiguous amino acids or less of a JAK 3 peptide of SEQ ID NO:16, wherein said peptide has been modified to contain the sequence of SEQ ID NO:15 which includes the JAK3 kinase.

Fuortes discloses a DNA sequence (please note that the disclosed sequence does not contain any uridylic acid, a nucleotide component of an RNA molecule) encoding a human clone NTK16 tyrosine kinase comprising a sequence of SEQ ID NO:15 being flanked by sequences containing about 22 identical amino acids of SEQ ID NO:16.

Accordingly, Fuortes anticipates the instant claim.

Claims 35-36 are rejected under 35 U.S.C. 102(a) as being anticipated by Kawamura et al. (Proc. Natl. Acad. Sci. 91:6374-6378, July 1994; Cited previously).

Kawamura et al. disclose a novel human L-JAK (JAK3) cDNA encoding for a kinase comprising two tandem nonidentical catalytic domains with a molecular weight of about 125,000 Da (See abstract, Fig. 1 and the disclosed GenBank accession no. U09607 at the bottom of page 6374). The disclosed cDNA molecule contains a DNA sequence (nucleotides 2852 to 3212; see attached sequence search report) encoding less than 400 contiguous amino acids of a JAK 3 peptide of SEQ ID NO: 16, as well as the sequence of SEQ ID NO:15 (see attached sequence search report). The sequence between nucleotides 2852 to 3212 reported by Kawamura also contains one conservative amino acid substitution (see querried Alanine at residue 936).

Accordingly, Kawamura et al. anticipate the instant claims.

Claim 42 is rejected under 35 U.S.C. 102(a) as being anticipated by Kawamura et al. (Proc. Natl. Acad. Sci. 91:6374-6378, July 1994; Cited previously) as evidenced by Kennell (Progr. Nucl. Acid Res. Mol. Biol. 11:259-301, 1971).

Kawamura et al. disclose a novel human L-JAK (JAK3) cDNA encoding for a kinase comprising two tandem nonidentical catalytic domains with a molecular weight of about 125,000 Da (See abstract, Fig. 1 and the disclosed GenBank accession no. U09607 at the bottom of page 6374). The disclosed cDNA molecule contains a DNA sequence (nucleotides 2852 to 3212; see attached sequence search report) encoding less than 400 contiguous amino acids of a JAK 3 peptide of SEQ ID NO: 16, as well as

the sequence of SEQ ID NO:15 (see attached sequence search report). The non-coding strand of the cDNA molecule disclosed by Kawamura et al. would hybridize to a DNA sequence encoding amino acids of a JAK3 peptide of SEQ ID NO:16 (not necessarily limited to any peptide length), and wherein said peptide has been modified to contain the sequence of SEQ ID NO:15 which includes the JAK 3 autophosphorylation site at the recited hybridization conditions because Kennell states that "it would appear that, depending on G + C content, the minimum size for a stable complex is from 10 to 20 nucleotides. The thermal stability rises sharply for longer lengths so that, depending on the G + C content, the stability of a complementary duplex of 25-50 nucleotides approaches that of any much longer complex" (page 261, first paragraph).

Accordingly, Kawamura et al. anticipate the instant claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 35, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over (Proc. Natl. Acad. Sci. 91:6374-6378, July 1994; Cited previously) in view of Avraham et al. (WO 93/15201).

Kawamura et al. disclose a novel human L-JAK (JAK3) cDNA encoding for a kinase comprising two tandem nonidentical catalytic domains with a molecular weight of about 125,000 Da (See abstract, Fig. 1 and the disclosed GenBank accession no. U09607 at the bottom of page 6374). The disclosed cDNA molecule contains a DNA sequence (nucleotides 2852 to 3212; see attached sequence search report) encoding less than 400 contiguous amino acids of a JAK 3 peptide of SEQ ID NO: 16, as well as the sequence of SEQ ID NO:15 (see attached sequence search report).

Kawamura et al. do not explicitly teach cloning the disclosed L-JAK cDNA sequence into an expression vector, or a host cell transformed with said expression vector, although Kawamura et al. state "It is anticipated that understanding the regulation of enzymatic activity and expression of L-JAK in NK cells and activated leukocytes will provide important insights into the molecular basis of lymphoid function." (page 6377, col. 2, bottom of last paragraph).

However, at the effective filing date of the present application, Avraham et al. already teach the identification and isolation of novel protein tyrosine kinase genes

present on human megakaryocytic and lymphocytic cells, and particularly introducing these genes into an appropriate vector/host system for expression though genetic engineering techniques (page 10, lines 29-31).

It would have been obvious for an ordinary skilled artisan to subclone the cDNA sequence disclosed by Kawamura et al. into an expression vector and transform a host cell with such a vector. The subcloning of a cDNA molecule into an expression vector and the making of host cells transformed with the expression vector are common techniques in molecular biology at the effective filing date of the present application as reflected by the teachings of Avraham et al.

The ordinarily skilled artisan would have been motivated to carry out the above modification for further biochemical characterization of the novel human JAK3 kinase taught by Kawamura et al., particularly the involvement of this kinase in various signal transduction pathways in NK cells and/or activated leukocytes.

Absence evidence to the contrary, there would have been a reasonable expectation of success for an ordinary skilled artisan to make an expression vector containing a human L-JAK (JAK3) cDNA, and an isolated host cell comprising the same.

Responses to Arguments

Applicants' argument related to the above rejections utilizing the reference of Kawamura et al. (Proc. Natl. Acad. Sci. 91:6374-6378, 1994) in the Amendment filed on August 28, 2001 in Paper No. 8 has been fully considered.

Applicants basically submitted the Declaration of Drs. Witthuhn and Ihle in Paper No. 8 to antedate the reference of Kawamura et al. However, Examiner does not find any evidence suggesting that prior to April 1994, Applicants have obtained an isolated DNA molecule comprising a DNA sequence encoding 400 contiguous amino acids or less of a JAK3 peptide of SEQ ID NO:26, wherein **said peptide contains the sequence of SEQ ID NO:15** which includes the JAK3 autophosphorylation site as claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 42 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,136,595. Although the conflicting claims are not identical, they are not patentably distinct from each other. This is because the instant claim encompasses the embodiment of claims 1-6 in the issued U.S. Patent No. 6,136,595. For example, an isolated DNA molecule comprising a DNA sequence encoding the JAK3 kinase amino acid sequence of SEQ

ID NO:16 or a JAK 3 kinase that is at least 80% or at least 80-99% or at least 95% homologous to the amino acid sequence of SEQ ID NO:16 of the issued U.S. Patent contains the non-coding or complementary strand that would hybridize to a DNA sequence encoding amino acids of a JAK 3 peptide of SEQ ID NO:16, wherein said peptide contains the sequence of SEQ ID NO:15, which includes the JAK3 autophosphorylation site under the recited stringent conditions.

Responses to Arguments

Applicants' argument related to the above rejection in the Amendment filed on December 09, 2002 in Paper No. 17 (page 7) has been fully considered.

Applicants argue simply that the claim of the current application is not obvious in view of the claims of U.S. patent NO. 6,136,595. Applicants' argument is respectfully found unpersuasive because an isolated DNA molecule (a double strand molecule) comprising a DNA sequence encoding a JAK3 kinase amino acid sequence sequence of SEQ ID NO:16 or a JAK 3 kinase that is at least 80% or at least 80-99% or at least 95% homologous to the amino acid sequence of SEQ ID NO:16 of the issued U.S. Patent contains the non-coding or complementary strand that would hybridize to a DNA sequence encoding amino acids of a JAK 3 peptide of SEQ ID NO:16, wherein said peptide contains the sequence of SEQ ID NO:15, which includes the JAK3 autophosphorylation site under the recited stringent conditions, particularly the non-coding or complementary strand of the isolated DNA molecule of the issued U.S. Patent

has **at least 50 contiguous nucleotides** complementary to the DNA sequence recited in claim 42 of the present application.

Conclusions

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Gerald Leffers, Jr., Ph.D., may be reached at (703) 305-6232, or SPE, Remy Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to LIE, Zeta Adams, whose telephone number is (703) 305-3291.

Quang Nguyen, Ph.D.

PATENT EXAMINER
Gerald G. Leffers Jr
A.U. 1636